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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,559	02/05/2002	C. Grant Willson	5119-07301	6950

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EXAMINER	
BEISNER, WILLIAM H	
ART UNIT	**PAPER NUMBER**
1744	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/068,559	WILLSON ET AL.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50,76,98-105,108-111,113-115 and 118-120* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50,76,98-105,108-111,113-115 and 118-120* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 108 and 118 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Independent claims 50 and 76 now include the limitations of previous claims 107 and 117 which include the limitation that the sensing element includes a receptor coupled to a polymeric body where the receptor is at least partially encapsulated within the polymeric body. Dependent claims 108 and 118 recite that the receptor is a nucleic acid. However, the originally filed disclosure fails to support the newly claimed limitation of an encapsulated nucleic acid. From Applicants' comments filed 12/26/06 (See page 12), it appears that the originally filed disclosure only supports the encapsulation of enzymes as receptors rather than nucleic acids.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 50, 76, 98-100, 102, 103, 108, 109, 111, 113 and 118-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al.(US 6,327,410) in view of Felder et al.(US 6,232,066), Chang et al.(US 6,350,620) or Ravkin et al.(US 2003/0008323) taken further in view of Pope (US 5,496,997) and Dakss et al.(US 4,269,648) and taken further in view of Peters, Jr. et al.(US 5,013,669).

The reference of Walt et al. discloses a method of sensing multiple analytes in a fluid that includes passing a fluid over a sensor array wherein the sensor array includes a plurality of sensing elements coupled to a supporting member, wherein a first portion of the sensing

elements are configured to produce a signal in the presence of a first analyte and wherein a second portion of the sensing elements are configured to produce a signal in the presence of a second analyte. The first and second portions of the sensing elements have unique predetermined optical signatures or tags wherein the optical signature or tag of the first portion of sensing elements is different from the optical signature or tag of the second portion of sensing elements. The method includes monitoring a spectroscopic change of the sensing elements as the fluid is passed over the sensing array, wherein the spectroscopic change is caused by the interaction of the analyte with the sensing element and determining the unique optical signature of the sensing elements that undergo a spectroscopic change (See column 13, lines 8-24, and column 15, line 64, to column 16, line 20).

With respect to claim 76, while the reference of Walt et al. disclose the use of unique predetermined optical signatures or tags that include the use of beads of different size (See column 18, lines 48-58, and column 19, lines 6-13), claim 76 differs by reciting that the method employs sensing elements (beads) of different shapes wherein the sensing element undergoing a spectroscopic change is identified by its shape.

The reference of Felder et al. discloses that it is known in the art to provide analyte detection beads with unique optical signatures or tags wherein the beads can be of different size or shape (See column 8, lines 49-56).

The reference of Chang et al. discloses that it is known in the art to provide analyte detection beads with unique optical signatures or tags wherein the beads can be of different size or shape (See column 3, lines 33-39).

The reference of Ravkin et al. discloses that it is known in the art to provide analyte detection beads with unique optical signatures or tags wherein the beads can be of different size or shape (See paragraphs [0096], [0137] and [0139]).

In view of any of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a unique optical signature with respect to the beads of the primary reference of Walt et al. using beads of different shapes for the known and expected result of providing an alternative means recognized in the art to achieve the same result, providing a means for optically distinguishing one sensing element from another. Use of beads of different shape rather than size would eliminate the need to employ different sized optical fibers required to detect the beads of different size. The same types of optical fibers would be capable of detecting beads of similar size but different shapes.

With respect to Claim 76, while the reference of Walt et al. discloses that immobilization of the different sensing elements to substrate (212) to form a sensing array includes placing the sensing elements in a liquid composition and curing the liquid composition to form a supporting member, wherein the sensing elements are at least partially embedded within the cured liquid composition (See column 17, line 47, to column 18, line 2), the claim further differs by reciting that the sensing elements are disposed **on or at an exterior surface of a cured liquid composition** for supporting the sensing elements.

The reference of Pope discloses that it is conventional in the art to immobilize an analysis particle (311) with respect to an optical fiber (312) using an adhesive composition (315).

The reference of Dakss et al. discloses that it is known in the art to immobilize a particle (11) with respect to an optical fiber (16) using a cured liquid composition (14) wherein the

particle is disposed on or at the exterior surface of the cured liquid composition (See column 3, lines 20-40).

In view of these disclosures, it would have been obvious to one of ordinary skill in the art to immobilize the analysis particles of the modified primary reference using a cured liquid composition as suggested by the references of Pope and Dakss et al. for the known and expected result of providing an alternative means recognized in the art to achieve the same result, immobilization of the analysis particles relative to the optical sensing components. This immobilization technique allows the analysis particle to be in direct contact with the test sample.

While the reference of Walt et al. discloses the use of porous polymer beads (See column 7, lines 20-41) and the use of a number of receptors that can be attached to the beads (See column 7, line 55, to column 12, line 62) the reference does not specifically disclose that the receptors are at least partially encapsulated within the polymer material forming the sensing elements.

The reference of Peters, Jr. et al. discloses that it is conventional in the art to encapsulate receptor molecules (See column 8, lines 54-67) within the pores of porous polymer bodies (See column 6, line 53, to column 7, line 37). The receptors are encapsulated within the pores of the bodies using a polymer (See column 7, line 48, to column 8, line 53).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to encapsulate the receptors of modified primary reference using the method disclosed by the reference of Peters, Jr. et al. for the known and expected results of avoiding the disadvantages associated with other known techniques for attaching the receptors to the solid support material (See column 1, line 5, to column 3, line 37).

With respect to claim 50, manufacture of the test device as suggested above would meet the method steps recited in claim 50.

With respect to claim 98, the method suggested by Peters, Jr. et al. includes polymerizing a monomer composition.

With respect to claim 99, the sensing elements are placed near the surface of the liquid composition (See column 17, line 47, to column 18, line 2).

With respect to claims 100 and 109, the reference of Walt et al. discloses that the sensing elements can be made from a polymer (See column 7, lines 20-41).

With respect to claims 102 and 111, the reference of Walt et al. discloses a number of receptors that can be used and produce a signal when they interact with an analyte (See column 13, lines 8-57).

With respect to claims 103 and 113, the modifications suggested in the combination of references discussed above would result in sensing elements that include non-spherical shape.

With respect to claims 108 and 118, the receptors can be a nucleic acid (See column 7, line 55, to column 8, line 3).

With respect to claims 119 and 120, the method suggested by the reference of Peters, Jr. et al. would result in the sensing element being formed using a mixture of monomer and receptor (See column 11, lines 1-30 of Peters, Jr. et al.).

5. Claims 50, 76, 98-105, 108-111, 113-115 and 118-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al.(US 6,327,410) in view of Felder et al.(US 6,232,066), Chang et al.(US 6,350,620) or Ravkin et al.(US 2003/0008323) taken further in view

of Pope (US 5,496,997) and Dakss et al.(US 4,269,648) and taken further in view of Kaetsu et al.(US 4,194,066).

The reference of Walt et al. discloses a method of sensing multiple analytes in a fluid that includes passing a fluid over a sensor array wherein the sensor array includes a plurality of sensing elements coupled to a supporting member, wherein a first portion of the sensing elements are configured to produce a signal in the presence of a first analyte and wherein a second portion of the sensing elements are configured to produce a signal in the presence of a second analyte. The first and second portions of the sensing elements have unique predetermined optical signatures or tags wherein the optical signature or tag of the first portion of sensing elements is different from the optical signature or tag of the second portion of sensing elements. The method includes monitoring a spectroscopic change of the sensing elements as the fluid is passed over the sensing array, wherein the spectroscopic change is caused by the interaction of the analyte with the sensing element and determining the unique optical signature of the sensing elements that undergo a spectroscopic change (See column 13, lines 8-24, and column 15, line 64, to column 16, line 20).

With respect to claim 76, while the reference of Walt et al. disclose the use of unique predetermined optical signatures or tags that include the use of beads of different size (See column 18, lines 48-58, and column 19, lines 6-13), claim 76 differs by reciting that the method employs sensing elements (beads) of different shapes wherein the sensing element undergoing a spectroscopic change is identified by its shape.

The reference of Felder et al. discloses that it is known in the art to provide analyte detection beads with unique optical signatures or tags wherein the beads can be of different size or shape (See column 8, lines 49-56).

The reference of Chang et al. discloses that it is known in the art to provide analyte detection beads with unique optical signatures or tags wherein the beads can be of different size or shape (See column 3, lines 33-39).

The reference of Ravkin et al. discloses that it is known in the art to provide analyte detection beads with unique optical signatures or tags wherein the beads can be of different size or shape (See paragraphs [0096], [0137] and [0139]).

In view of any of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a unique optical signature with respect to the beads of the primary reference of Walt et al. using beads of different shapes for the known and expected result of providing an alternative means recognized in the art to achieve the same result, providing a means for optically distinguishing one sensing element from another. Use of beads of different shape rather than size would eliminate the need to employ different sized optical fibers required to detect the beads of different size. The same types of optical fibers would be capable of detecting beads of similar size but different shapes.

With respect to Claim 76, while the reference of Walt et al. discloses that immobilization of the different sensing elements to substrate (212) to form a sensing array includes placing the sensing elements in a liquid composition and curing the liquid composition to form a supporting member, wherein the sensing elements are at least partially embedded within the cured liquid composition (See column 17, line 47, to column 18, line 2), the claim further differs by reciting

that the sensing elements are disposed **on or at an exterior surface of a cured liquid composition** for supporting the sensing elements.

The reference of Pope discloses that it is conventional in the art to immobilize an analysis particle (311) with respect to an optical fiber (312) using an adhesive composition (315).

The reference of Dakss et al. discloses that it is known in the art to immobilize a particle (11) with respect to an optical fiber (16) using a cured liquid composition (14) wherein the particle is disposed on or at the exterior surface of the cured liquid composition (See column 3, lines 20-40).

In view of these disclosures, it would have been obvious to one of ordinary skill in the art to immobilize the analysis particles of the modified primary reference using a cured liquid composition as suggested by the references of Pope and Dakss et al. for the known and expected result of providing an alternative means recognized in the art to achieve the same result, immobilization of the analysis particles relative to the optical sensing components. This immobilization technique allows the analysis particle to be in direct contact with the test sample.

While the reference of Walt et al. discloses the use of porous polymer beads (See column 7, lines 20-41) and the use of a number of receptors that can be attached to the beads (See column 7, line 55, to column 12, line 62) the reference does not specifically disclose that the receptors are at least partially encapsulated within the polymer material forming the sensing elements.

The reference of Kaetsu et al. discloses that is it known in the art to form porous polymer particles that include biological active materials by mixing a monomer and the receptors prior to

forming the final porous body (See column 3, lines 10-53) wherein the biological active material (receptor) is at least partially encapsulated in the polymer body formed.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to encapsulate the receptors of modified primary reference using the method disclosed by the reference of Kaetsu et al. for the known and expected results of avoiding the disadvantages associated with other known techniques for encapsulating or attaching the receptors to the solid support material (See column 1, line 5, to column 2, line 7).

With respect to claim 50, manufacture of the test device as suggested above would meet the method steps recited in claim 50.

With respect to claim 98, the method suggested by Kaetsu et al. includes polymerizing a monomer composition.

With respect to claim 99, the sensing elements are placed near the surface of the liquid composition (See column 17, line 47, to column 18, line 2).

With respect to claims 100 and 109, the reference of Walt et al. discloses that the sensing elements can be made from a polymer (See column 7, lines 20-41).

With respect to claims 101, 104, 105, 110, 114 and 115, the reference of Kaetsu et al. discloses that the polymer body can comprise polyethylene glycol, including polyethylene glycol diacrylate (See column 5, lines 45-50).

With respect to claims 102 and 111, the reference of Walt et al. discloses a number of receptors that can be used and produce a signal when they interact with an analyte (See column 13, lines 8-57).

With respect to claims 103 and 113, the modifications suggested in the combination of references discussed above would result in sensing elements that include non-spherical shape.

With respect to claims 108 and 118, the receptors can be a nucleic acid (See column 7, line 55, to column 8, line 3).

With respect to claims 119 and 120, the method suggested by the reference of Kaetsu et al. would result in the sensing element being formed using a mixture of monomer and receptor (See column 11, lines 1-30 of Peters, Jr. et al.).

Response to Arguments

6. With respect to the rejection of Claims 50, 76 and 98-118 under 35 U.S.C. 103(a) as being unpatentable over Walt et al.(US 6,327,410) in view of Felder et al.(US 6,232,066), Chang et al.(US 6,350,620) or Ravkin et al.(US 2003/0008323) taken further in view of Pope (US 5,496,997) and Dakss et al.(US 4,269,648), this rejection has been with drawn in view of Applicants comments (See pages 7-13 of the response dated 12/26/06) that the reference of Walt et al. does not teach or fairly suggest the claim limitation that the receptor is "at least partially encapsulated within the polymeric body".

A new ground of rejection has been made over the previous combination of references include either of the reference of Peters, Jr. et al. (5,013,669) or Kaetsu et al.(US 4,194,066)

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

William H. Beisner
Primary Examiner
Art Unit 1744

WHB